

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE**

Tri-Cities Holdings LLC et al.,	)	
	)	
Plaintiffs,	)	Case No. 13-cv-669
	)	
v.	)	Chief Judge Haynes
	)	
Tennessee Health Services and Development Agency et al.,	)	
	)	
Defendants.	)	
_____	)	

**DECLARATION OF STEVEN W. KESTER**

I, Steven W. Kester do declare under penalty of perjury and if called as a witness would testify as follows:

**BACKGROUND**

1. I am over the age of 18 and a resident of Gwinnett County, Georgia. I have lived in Georgia from 1990 to the present.
2. I attended the Georgia Institute of Technology from 1982 to 1986 where I received a degree in Electrical Engineering.
3. I attended the University of Pennsylvania, Wharton School of Business where I received a Masters of Business Administration in 1990.
4. I worked for Anderson Consulting (now Accenture) for 10 years where I focused in the service industry.

5. In 2007, I co-founded the Crossroads Treatment Centers, opiate addiction treatment programs, which include methadone maintenance therapy. At various times during my work building this business, I worked closely with physicians and staff members to implement an effective opiate replacement therapy program that helps thousands of opiate-addicted persons break the cycle of addiction.

6. Presently, I am President and Manager of Tri-Cities Holdings LLC ("TCH"), the Plaintiff in the above-captioned matter.

### **OVERVIEW OF TCH'S MISSION**

7. I have been an owner and officer of Crossroads Treatment Clinics - a chain of nine opiate treatment programs. Crossroads has provided treatment to thousands of opiate addicted people in Georgia, South Carolina, North Carolina, Tennessee and Virginia.

8. The Crossroads programs are valued and respected by members of the communities we serve. The programs have operated continuously and have passed rigorous licensing, certifications and inspections at the state and federal level.

### **THE OTP PROGRAM**

9. This case involves an Opiate Treatment Program ("OTP") that TCH intends to operate at 4 Wesley Court, Johnson City, Tennessee ("Proposed Location").

10. A key purpose of the Program is to provide outpatient services to treat addiction through the use of medication along with counseling and education.

11. TCH provides on-site skilled personnel to provide educational training to the participants. OTP clients will receive between one hour and two and one half hours of on-site counseling, education and behavior modification each month.

12. As a condition of participating in the Program, residents must abide by program rules, including test negative for illegal drugs, not divert or sell their prescribed medicine, attend counseling, participate in medicine call-back procedures, and refrain from violence and/or illegal activities on-site. If a resident violates these conditions, s/he will be discharged from the Program.

13. On March 5, 2013, TCH has applied for a Certificate of Need (“CON”) to the Tennessee Health Services and Development Agency (“HSDA”) to operate a “Non-Residential Methadone Treatment Facility” ( aka “methadone clinic”) at 4 Wesley Court, Johnson City, Tennessee.

14. After approval of TCH’s CON Application, TCH will apply for a license from the Tennessee Department of Health (“TDH”).

15. TCH has secured an option lease to lease 4 Wesley Court which is required under the terms of the CON and TDH’s license.

16. At least twelve other OTPs have obtained CON’s and applicable licenses and are presently operating in other parts of Tennessee including Knoxville and locations west of Knoxville.

17. Although not part of HSDA’s criteria for granting an application for a CON, Johnson City’s unlawful refusal to grant zoning approval of TCH’s clinic at 4 Wesley Court is interfering with TCH’s application for a CON and causing TCH irreparable injury. Johnson City’s unlawful refusal to grant TCH zoning approval also potentially interferes with TCH’s application for a license to TDH and causing TCH irreparable injury.

### **FACTUAL BACKGROUND**

18. The nearest Opioid Treatment Program provider available to residents of the Johnson City area is located more than 50 miles away in Weaverville, North Carolina. The nearest in-state clinic is in Knoxville, Tennessee which is more than 100 miles away.

19. Individual Plaintiffs, like hundreds of other opiate-addicted residents of the Johnson City area, currently must drive between 100 miles and 200 miles roundtrip for treatment to an Opioid Treatment Program located in either Weaverville, North Carolina, or Knoxville, Tennessee because there is not an Opioid Treatment Program in or near Johnson City.

20. The Individual Plaintiffs are disabled under the Rehabilitation Act and the ADA.

21. The Individual Plaintiffs are prospective clients of TCH's proposed clinic location in Johnson City.

22. The Zoning Ordinance provides the definition of a methadone clinic as follows: "Methadone Treatment Clinic: A licensed facility for the counseling of patients and the distribution of methadone for outpatient, non-residential purposes only."<sup>1</sup>

23. Johnson City's zoning ordinance prohibiting the location of methadone treatment facilities in certain locations and with the following restrictions:

- a. The Zoning Ordinance limits methadone treatment clinics to areas zoned MS-1.<sup>2</sup>
- b. The facility shall be fully licensed/certified by the appropriate regulating state agency;
- c. A certificate of need shall be obtained from the appropriate state agency prior to review by the Board of Zoning Appeals;

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<sup>1</sup>See Zoning Code, Art. II. Definition of Terms.

<sup>2</sup> See Zoning Code Section 6.13 - MS-1 Medical Service District.

- d. The facility shall not be located within two hundred (200) feet of a school, day-care facility, or park as measured from property line to property line;
- e. The facility shall not be located within two hundred (200) feet of any establishment that sells either on-premise or off-premise alcoholic beverages as measured from property line to property line;
- f. The hours of operation shall be between 7:00 a.m. and 8:00 p.m.;
- g. The facility shall be located on and primary access shall be from an arterial street.

See Zoning Ordinance Code Section 6.13.3.4.

24. Johnson City places no similar restrictions on any non-drug addiction treatment-related business.

25. Land zoned MS-1 comprises less than 1% of total available land in Johnson City.

26. Therefore, the requirement that methadone treatment clinics locate in MS-1 areas (Section 6.13) combined with restrictions to location on arterial streets (Section 6.13.3.4, para. F.) already limits the land available for methadone clinics to well below 1% of the total land area of Johnson City. Johnson City offers no policy reason for doing this and restricts no other business in this way.

27. Further, after reducing the available area available to methadone clinics to less than 1% of available land, the Zoning Ordinance adds on additional restrictions which include, without limitation, prohibiting the clinic from locating within:

- a. two hundred (200) feet of a “school, day-care facility, or park as measured from property line to property line;” and

- b. two hundred (200) feet of “any establishment that sells either on-premise or off-premise alcoholic beverages as measured from property line to property line.”

28. The practical result of these and other restrictions is that it is impossible for TCH to locate a methadone treatment clinic in Johnson City.

29. The comprehensive, multiple distance requirements imposed on methadone clinics by the Zoning Ordinance are not imposed on non-drug treatment-related businesses.<sup>3</sup>

30. Beginning in February 2013, TCH began its search for an appropriate site to operate an Opioid Treatment Program within Johnson City. TCH selected a site known as 4 Wesley Court. This location is zoned as “MS-1 Medical Services District” which the Zoning Ordinance states is intended for “medical facilities, services, and related support uses”. See Zoning Ordinance Section 6.13.1 INTENT. The occupancy permit then in place for the site included use as a medical facility.

31. TCH has obtained an option to lease, use and operate a methadone clinic at the address known as 4 Wesley Court which is inside Johnson City.

32. TCH’s Manager Steve Kester has surveyed all properties in Johnson City zoned both MS-1 and located on an arterial street and he unable to find any property that was both available and suitable.

33. Based on my review of all available MS-1 zoned property for lease in Johnson City, the only suitable property for TCH’s OTP clinic is 4 Wesley Court.

34. On March 13, 2013, TCH filed an application for a special exception permit and a variance permit to operate a methadone clinic at 4 Wesley Court, Johnson City, Tennessee.

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<sup>3</sup> A non-methadone “Substance Abuse Treatment Facility” faces certain restrictions similar to methadone clinics, but no distance restrictions. Zoning Ordinance Section 6.13.3.5.

35. At that time, TCH filed a request for a variance and/or special exception related to the Zoning Ordinance's requirement to limit operations before 7AM and, instead, allow TCH to open at 5AM Monday-Saturday because many of TCH's prospective patients work and have to visit TCH's clinic before work to get their medication. This is common practice for OTPs across the country to accommodate the work, school, and family obligations of patients.

36. At that time, TCH filed a request for a variance and/or special exception related to the Zoning Ordinance's requirement to limit methadone clinics to arterial streets because TCH was unable to find any acceptable location zoned MS-1 and also located on an arterial street.

37. At that time, TCH filed a request for a variance and/or special exception related to the Zoning Ordinance's requirement to prohibit the Board of Zoning Appeals from hearing requests for zoning of methadone clinics before the issuance of a Certificate of Need by the State of Tennessee because the restriction only applied to methadone clinics and no other business.

38. On March 21, 2013, TCH delivered a letter to Johnson City outlining TCH's requests for an accommodation under the ADA and the Rehabilitation Act. See Exhibit I. In this letter, TCH specifically offered to meet with officials of Johnson City, including the Mayor, City Manager, and other City leaders, to attempt to work out an accommodation to allow TCH to locate and open a methadone clinic.

39. In this March 21, 2013 letter, TCH informed Johnson City of its duty to accommodate TCH to allow it to open and operate an Opioid Treatment Program under the Americans with Disabilities Act and the Rehabilitation Act of 1973.

40. All Defendants rejected TCH's request in the letter to meet and attempt to work out an accommodation to allow TCH to locate and open a methadone clinic at 4 Wesley Court.

41. TCH made additional requests to Johnson City to meet and attempt to work out an accommodation to allow TCH to locate and open a methadone clinic at 4 Wesley Court, all Defendants rejected TCH's requests.

42. On April 9, 2013, a hearing was scheduled to consider TCH's variance and special exception requests.

43. Before the hearing began, TCH asked the Board of Zoning Appeals to continue the hearing set that day to a later date which would allow more time to work out an accommodation.

44. The Board of Zoning Appeals denied TCH's request for a continuance -- despite the fact that under the Zoning Ordinance the Board of Zoning Appeals has no authority to review a special exception permit or variance request for a methadone clinic prior to the clinic obtaining a Certificate of Need by the State of Tennessee.<sup>4</sup>

45. On April 9, 2013, TCH presented to the Board of Zoning Appeals a request to grant the requests for a variance permit and/or special exception permit as a reasonable accommodation under the Americans with Disabilities Act and the Rehabilitation Act of 1973.

46. At the April 9, 2013 hearing, TCH asked the Board of Zoning Appeals for a reasonable accommodation for (a) a variance with regard to the arterial street requirement as there were no other locations zoned MS-1 on an arterial street available for lease with adequate parking; and, (b) a variance with regard to the hours of operation requirement to allow TCH patients who work to be able to obtain treatment before going to work; and (c) a variance related to the requirement to obtain a Certificate of Need prior to the board hearing the request.

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<sup>4</sup>Zoning Ordinance Section 6.13.3.4 ("A certificate of need shall be obtained from the appropriate state agency prior to review by the Board of Zoning Appeals.").



47. At the April 9, 2013 hearing, the Individual Plaintiffs, through their attorney, explained that they were Johnson City area residents, that they were addicted to opiates, that they were disabled under the ADA and the RA, that they were presently required to drive more than 100 miles round trip to an Opioid Treatment Program in North Carolina because there was no treatment facility nearby, that the TCH clinic was required to provide the Individual Plaintiffs with reasonable access to treatment, and that by refusing to afford a reasonable accommodation to TCH's clinic, Johnson City would be violating both the ADA and the Rehabilitation Act.

48. At the April 9, 2013 hearing, the Individual Plaintiffs requested that Johnson City grant TCH's requests and reasonably accommodate TCH to allow it to open an Opioid Treatment Program which would provide the Individual Plaintiffs with reasonable access to treatment.

49. At the April 9, 2013 hearing, the Board of Zoning Appeals stated it had no authority to waive any of the zoning requirements although it proceeded to waive the requirement to hear a request for zoning a methadone clinic prior to issuance of a Certificate of Need.

50. On April 9, 2013, the Board of Zoning Appeals denied all of TCH's requests for a reasonable accommodation related to its variance and/or special exception requests.

51. In denying TCH's request for a permit and zoning variances, Johnson City has demonstrated a conscious indifference to the rights of TCH and the Individual Plaintiffs under the ADA and the Rehabilitation Act of 1973, entitling TCH and the Individual Plaintiffs to actual and consequential damages in an amount to be proven at trial.

52. TCH is prepared to open its proposed drug treatment center within one hundred and twenty (120) days, or sooner, of this court compelling Defendants to issue TCH a business

permit to operate a methadone clinic in Johnson City and TCH obtaining the Certificate of Need from the Tennessee Health Services and Development Agency and a license from the Tennessee Department of Health.

53. Johnson City has continued to discriminate against persons with drug addictions being treated with methadone in refusing to grant TCH's application for use and occupancy permits.

54. Plaintiffs have exhausted their administrative remedies as to Johnson City.

55. Numerous attempts to establish a clinic in the Johnson City area has prompted fierce opposition and have been blocked. Indeed, of only twelve methadone treatment facilities in the entire state of Tennessee, none are located in the Tri Cities Area—the nearest treatment clinics remain 50-100 miles away.

56. Several other providers have tried without success to site clinics in the Northeast Tennessee area in 2012, 2010 and twice in 2003. The only company to go through the CON process had their application approved, only to be overturned on a technicality.

57. Because of Defendants' discriminatory reaction and behavior, TCH has expended time and financial resources and has lost the opportunity to conduct its business and provide a much-needed service.

58. In its application for a Certificate of Need, the Tennessee Health Services and Development Agency ("HSDA") includes a specific section evaluating the economic feasibility of the proposed clinic. See Exhibit N.

59. In its application for a Certificate of Need, HSDA references multiple economic feasibility requirements set forth in the Tennessee Guidance for Growth--Criteria and Standards for Certificate of Need (2000 Edition)." See Exhibit O, pp. 4, 8, 21, 26.

60. The CON application, referencing the Guidelines for Growth, requires TCH to show its ability to meet Tennessee Department of Mental Health licensure requirements. See Exhibit N, p. 12, referencing Guidelines for Growth, Exhibit O, p 26.

61. In its application for a Certificate of Need, HSDA requested that TCH provide it with all applicable local zoning regulations.

62. In its application for a Certificate of Need, HSDA specifically requested that TCH provide it information showing that TCH has obtained local zoning approval from Johnson City.

63. Failing to obtain zoning approval will adversely affect TCH's application for a Certificate of Need due to its negative affect on economic feasibility of the proposed clinic.

64. TCH's CON application was considered by HSDA on June 26, 2013.

65. Plaintiff Tri-Cities Holdings LLC is a Georgia limited liability company with its principal place of business at 6555 Sugarloaf Parkway, Suite 307-137, Duluth, Georgia 30097.

66. TCH intends to meet the standards to establish an OTP in Johnson City in accordance with applicable federal and state law and regulations.

67. TCH sues on its own behalf and on behalf of its prospective patients.

68. Plaintiff Jane Doe Nos. 1-2 are opiate-addicted residents of the greater Johnson City area and are prospective patients of TCH.

69. Plaintiffs John Doe Nos. 1-6 are opiate-addicted residents of the greater Johnson City area and are prospective patients of TCH.

70. HSDA is state agency created by the Tennessee legislature in 2002.

71. HSDA is responsible for regulating the health care industry in Tennessee through the CON Program. A CON is a permit for the establishment or modification of a health care

institution, facility or service, purchase of major medical equipment, or establishment of certain services at a designated location.

72. HSDA heard and considered TCH's CON application at its principal office located at The Frost Building, 3rd Floor, 161 Rosa L. Parks Boulevard, Nashville, TN 37243.

73. For more than forty years, MMT has been considered the standard of care in the treatment of opioid addiction.

74. Presently, MMT is the standard of care for treatment of opiate-addicted pregnant women.

75. Presently, there are approximately 1,300 OTP clinics offering MMT treatment across the United States.

76. Presently, there are at least twelve OTP clinics offering MMT treatment in Tennessee as far east as Knoxville, Tennessee.

77. Presently, MMT treatment is not available anywhere within a 50 radius of Johnson City, Tennessee.

78. Presently, MMT treatment is not available in Johnson City, Tennessee and a person requiring MMT treatment must drive more than 100 miles roundtrip to an OTP clinic in North Carolina.

79. Presently, MMT treatment is not available in Johnson City, Tennessee and a person requiring MMT treatment in Tennessee must drive more than 200 miles roundtrip to an OTP clinic in Knoxville, Tennessee.

80. Presently, the Individual Plaintiffs must drive hundred-mile-plus round trips to the nearest OTP clinic in North Carolina as often as daily.

81. A person required to drive 100 miles roundtrip daily for medical treatment is not be considered to have reasonable access to treatment.

82. The lack of any OTP clinic within fifty (50) miles in any direction from Johnson City denies them reasonable access to treatment for their disability.

83. TCH is seeking a permit to provide comprehensive, medically supervised and licensed outpatient MMT directed at rehabilitating persons living in the Johnson City area who require treatment to alleviate their opiate dependency.

84. Prescription drug abuse is a national problem, and particularly acute in Tennessee.

85. Numerous studies have found that addiction to heroin and other opiates is a chronic medical illness that produces significant and lasting changes in brain chemistry and function.

86. Numerous studies have also found that this medical illness can be effectively treated in a program offering MMT. For example, in 1997, an expert panel convened at a National Institutes of Health (NIH) Consensus Development Conference on Effective Medical Treatment of Heroin Addiction concluded that opiate addiction is a medical disorder that can be effectively treated in a MMT program. Methadone, by acting on opiate receptors in the brain that are implicated in the changes in brain chemistry and function associated with drug dependence, reduces patients' cravings for opiates and blocks its effects, thereby enabling patients to lead productive lives. Some patients stay on methadone indefinitely, while others move from methadone to abstinence.

87. Opioid maintenance treatment of opiate addiction, including methadone maintenance, has been found to be effective in curtailing drug use, reducing crime, enhancing

social productivity, and preventing both overdose deaths and the spread of infectious diseases, including HIV.

88. Individual Plaintiffs, like hundreds of other opiate-addicted residents of the Johnson City area, currently must drive between 100 miles and 200 miles roundtrip for treatment to an Opioid Treatment Program located in either Weaverville, North Carolina, Boone, North Carolina, or Knoxville, Tennessee because there is not an Opioid Treatment Program in or near Johnson City.

89. The Individual Plaintiffs' drive must be made as often as daily to avoid serious withdrawal symptoms common to opiate-addicted persons: tremors; cramps; muscle and bone pain; chills; perspiration (sweating); tachycardia (rapid heartbeat); itching; Restless Legs Syndrome; flu-like symptoms; Rhinitis (runny, inflamed nose); yawning; sneezing; vomiting; Diarrhea; weakness; Akathisia (a profoundly uncomfortable feeling of inner restlessness).

90. The Individual Plaintiffs' drive to and from an Opioid Treatment Program outside the Tri-Cities Area must be done in all weather and under dangerous driving conditions on mountain roads during rain, sleet or snow.

91. TCH seeks to bring standard of care MMT treatment to the Proposed Service Area for the first time.

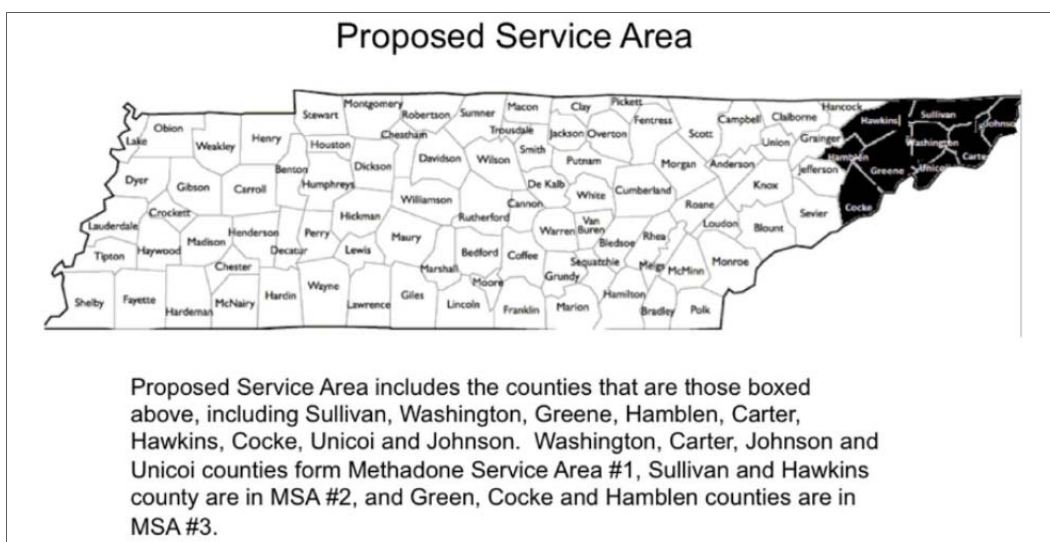
92. TCH seeks to treat clients with a primary dependence on opiates.

93. TCH will use the latest medical technologies, including methadone maintenance treatment, to address the physical symptoms of the addiction in combination with the psychotherapeutic interventions proven most effective to address the emotional, cognitive and behavioral symptoms of its patients.

94. TCH's programs will be "supervised rehabilitation programs" for persons with disabilities as described under federal law which, importantly, would introduce standard of care MMT into the Proposed Service Area for the first time.

95. TCH's CON application indicated a Proposed Service Area is shown in the darkened areas of the map below ("Proposed Service Area").

96. The nine counties comprising the Proposed Service Area are the northeastern counties of Tennessee: Sullivan, Washington, Greene, Hamblen, Carter, Hawkins, Cocke, Unicoi, and Johnson counties.



97.

98. These counties comprises not one, but three "Methadone Service Areas" that the State of Tennessee's "Methadone Task Force" in 2001 declared that every resident of Tennessee should have reasonable access to MMT and established pre-defined areas that should have at least one OTP.<sup>5</sup> Again, a present there are no OTPs and no access to MMT treatment in the Proposed Service Area.

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<sup>5</sup> The report designated 23 distinct Methadone Service Areas (MSA) within Tennessee to assure reasonable patient access to a methadone program. MSA was defined as a county or constellation of contiguous counties in the state that comprise a sufficient general population making it likely that a minimum number of opiate dependent persons reside in the MSA who

99. Numerous studies have found that addiction to heroin and other opiates is a chronic medical illness that produces significant and lasting changes in brain chemistry and function. Numerous studies have also found that this medical illness can be effectively treated in a MMT program. For example, in 1997, an expert panel convened at a National Institutes of Health (NIH) Consensus Development Conference on Effective Medical Treatment of Heroin Addiction concluded that opiate addiction is a medical disorder that can be effectively treated in employing standard of care methadone maintenance treatment (“MMT”).

100. Presently, there is no OTP clinic offering MMT in the Proposed Service Area.

101. In any other field of medicine, bringing standard of care treatment into a community is met with open arms. But for some reason, standard of care for opiate-addiction is not welcome in East Tennessee.

102. After this Court compels Defendants to issue TCH a CON, and all necessary zoning and local business permits to operate its OTP clinic in Johnson City, TCH is prepared to open its proposed OTP clinic with all deliberate speed, including TCH obtaining a license from the Tennessee Department of Mental Health and Substance Abuse Services for operation of its OTP.

103. East Tennessee is in the midst of a human catastrophe caused by opiate addiction which is exacerbated by the lack of available standard of care treatment options.

104. More than 1,700,000 Americans are opioid dependent according to the 2007 National Survey on Drug Use and Health Report.<sup>6</sup>

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seek treatment could support a program. The minimum population foundation was balanced with the need to establish geographic boundaries such that patients living within the MSA would reside within an hour drive one-way to a treatment program if the program were established in the heart of the MSA.

<sup>6</sup> 2007 *National Survey on Drug Use and Health: National Findings*. DHHS Publication No.



105. At the CON hearing, TCH presented grim statistics on the unfolding catastrophe from opioid addiction in Tennessee:

106. Tennessee has one of the highest rates of prescription drug abuse in the nation.

107. Drug overdose deaths in 2010 represent an increase of 250% over the 10 year time period.

108. Fifty-one (51) pills of hydrocodone are prescribed each year for every Tennessean above the age of twelve.

109. Twenty-one (21) pills of oxycodone are prescribed each year for every Tennessean above the age of twelve.

110. Per-capita oxycodone sales increased five- or six-fold in most of Tennessee during the decade.

111. Opioid abuse in Tennessee is greater than abuse of marijuana or crack/cocaine.

112. Prescription drug abuse hits every profession and every socioeconomic level.

113. Percentage of Tennessee children entering custody with related substance abuse problem increased from 19% to 33%.

114. Estimated costs of caring for these children increased from \$29 million to over \$52 million.

115. Every year in Tennessee, opioid dependence causes 2,000 new people to seek MMT treatment at OTP clinics.

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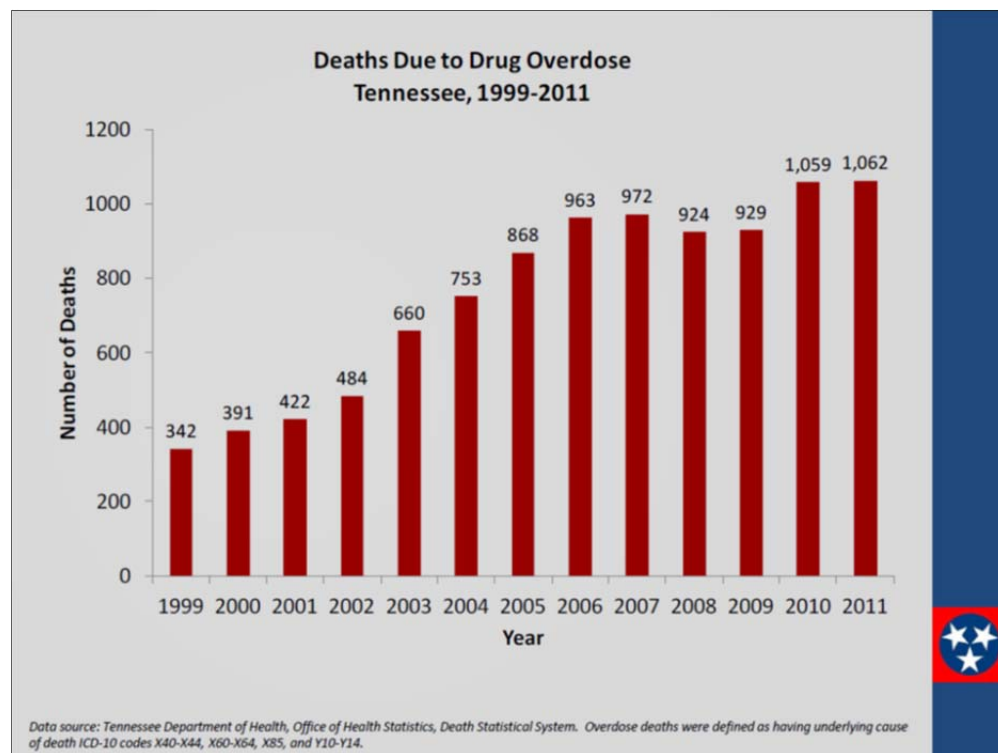
(SMA) 08-4343. Rockville, MD: HHS, Substance Abuse and Mental Health Services Administration, Office of Applied Studies, September 2008, p. 71.

116. In 2003, a CON was granted for the proposed area when the death rate was less than half its current rate, but it was ultimately derailed on a procedural technicality<sup>7</sup> in part by efforts of Johnson City community leaders.

117. Over the next ten years (as in the last decade), more than 10,000 drug overdose deaths will occur in Tennessee, and 1,000 drug overdose deaths will occur in East Tennessee.

118. Since 2003, approximately 1,000 people have died of drug overdoses in the Proposed Service Area.

119. The death toll rate is on course to soon double at present growth rates.



120.

121. These death figures reveal an unprecedented disaster both in the state as a whole and the Proposed Service Area in particular. Even now, more than 1,000 die each year from drug overdose in Tennessee (1,062 in 2011).

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<sup>7</sup>On appeal, an administrative law judge found the unanimous vote to approve the CON was void because the panel lacked of a quorum due to a panel member recusing himself instead of abstaining.

122. TCH's Proposed Service Area population is approximately 9.3% of the state population.

123. Approximately 100 people in the Proposed Service Area are projected to die from drug overdose each year into indefinite future (one death every 2.9 days).

124. Approximately 1,000 will die in the Proposed Service Area from drug overdose over the next ten years.

125. Assuming growth rate of drug overdose deaths continues, deaths in Proposed Service Area will exceed 1,500 over the next ten years.

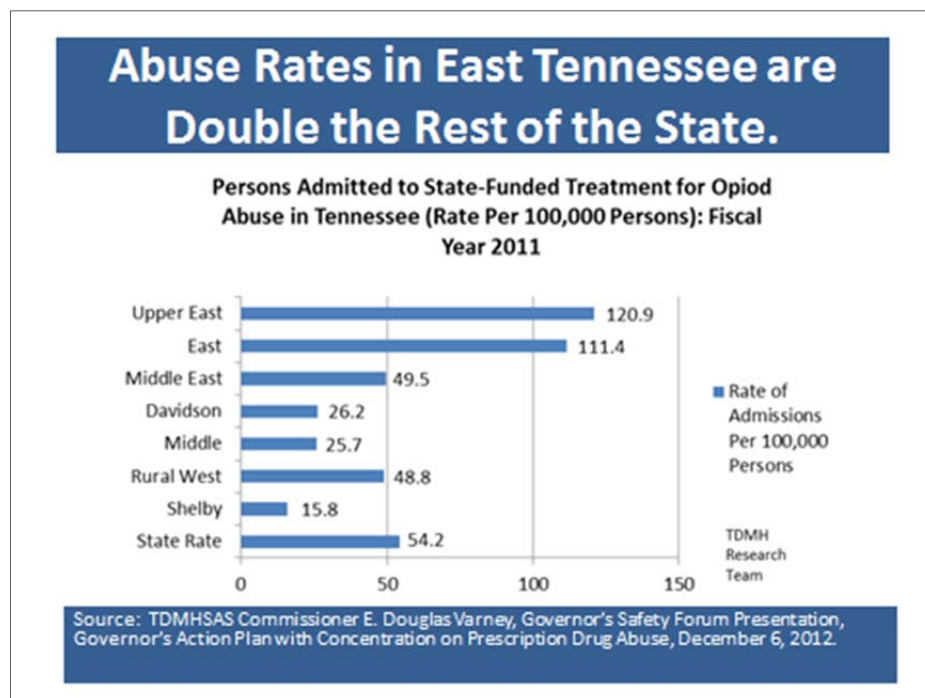
126. In fact, the opiate-addiction epidemic in Tennessee, and in East Tennessee in particular, is so bad that it's killing residents at a pace exceeding that of deaths of American service personnel in the Iraq and Afghanistan wars.

<b>Tennessee Drug Overdose Death Toll Exceeds Iraq and Afghanistan Wars</b>		
	<b>Total Deaths Since 2003</b>	<b>Deaths Most Recent Year</b>
<b>Tennessee (2003-2011)</b>	<b>8,193</b>	<b>1,065</b>
<b>Proposed Service Area</b>	<b>762</b>	<b>99</b>
<b>Iraq (2003-2013)</b>	<b>4,486</b>	<b>54</b>
<b>Afghanistan (2003-2013)</b>	<b>2,243</b>	<b>93</b>
<b>Source: Tennessee Statistics through 2011—Comm. D. Varney Presentation, Dec. 2012. Iraq and Afghanistan through 2013, U.S. casualties, from <a href="http://www.icasualties.org">www.icasualties.org</a>; Proposed service area is approx. 600,000 which is 9.3% of total Tennessee population of 6,450,000.</b>		

127.

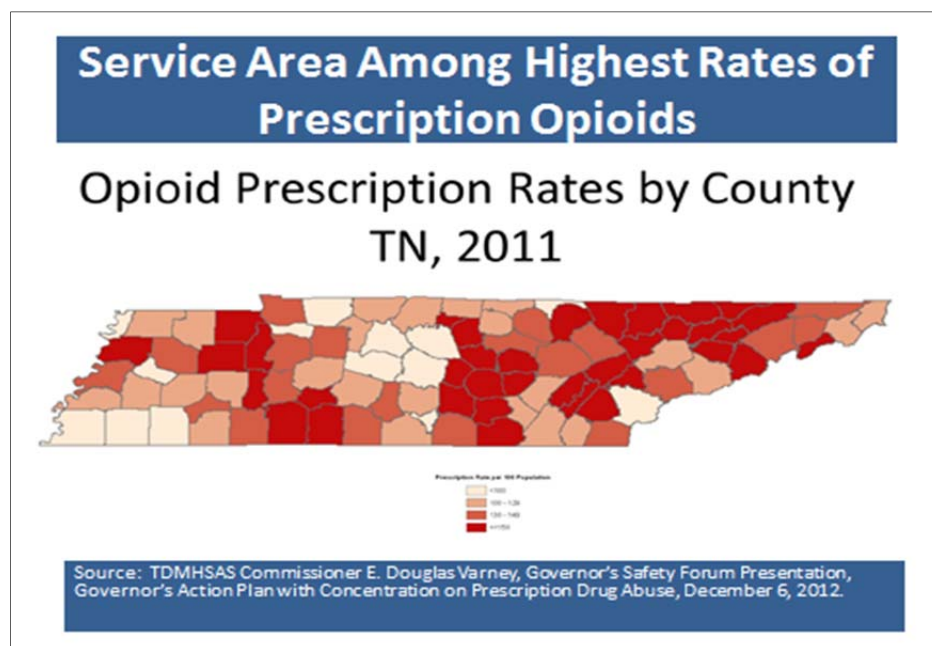
128. Presently, there appears no end in sight to these “war zone” levels of death from drug overdoses in Tennessee in general and East Tennessee in particular.

129. As presented by TCH at the CON hearing, the drug abuse problem in East Tennessee is more than twice as severe as the rest of the state:



130.

131. As presented by TCH at the CON hearing, some of the highest rates of prescription opioids in the state are in East Tennessee:



132.

133. Projecting state-wide data, an estimated 24,000 people over 12 years old abuse opiates in the Proposed Service Area.<sup>8</sup>

**134. East Tennessee is experiencing a catastrophe of large numbers of opiate-addicted pregnant women in the midst of a complete absence of standard of care MMT treatment in the Proposed Service Area.**

135. Nearly 48,000 women died of prescription painkiller overdoses between 1999 and 2010 in the United States.<sup>9</sup>

136. More than 5 times as many women died from prescription painkiller overdoses in 2010 as in 1999.<sup>10</sup>

137. Deaths from prescription painkiller overdoses among women have increased more than 400% since 1999, compared to 265% among men.<sup>11</sup>

138. For every woman who dies of a prescription painkiller overdose, thirty (30) go to the emergency room for painkiller misuse or abuse.<sup>12</sup>

139. Opiate addiction among pregnant women in Tennessee is exploding as it is nationwide.<sup>13</sup>

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<sup>8</sup> Almost 5% of all Tennessee residents over 12 abused opiates in the last year. State of Tennessee Health Plan 2012; TDMHSAS Commissioner E. Douglas Varney, Governor's Safety Forum Presentation, Governor's Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012. The proposed service area is approximately 600,000 people representing 9.3% of total state population of 6,450,000. Over 12 equals 80% of total population (approx) ([http://www.censusscope.org/us/s47/chart\\_age.html](http://www.censusscope.org/us/s47/chart_age.html)). 80% of 5% of 6,450,000 equals 258,000. 80% of 5% of 600,000 service area equals 24,000

<sup>9</sup> Center for Disease Control (2013)(<http://www.cdc.gov/vitalsigns/PrescriptionPainkillerOverdoses/>)

<sup>10</sup> Id.

<sup>11</sup> Id.

<sup>12</sup> Id.

<sup>13</sup> New York Times, May 1, 2012 "Prescription Drug Abuse Soars Among Pregnant Women." [http://www.nytimes.com/2012/05/01/health/research/prescription-drug-abuse-soars-among-pregnant-women.html?\\_r=0](http://www.nytimes.com/2012/05/01/health/research/prescription-drug-abuse-soars-among-pregnant-women.html?_r=0)

140. East Tennessee has more than 50% higher rates of opiate-addicted pregnant women that in the rest of the state.<sup>14</sup>

141. In fact, in one recent seven month period, one hundred and thirty (130) opiate-addicted pregnant women presented themselves at medical offices and emergency rooms in the Johnson City, Tennessee area seeking treatment to save their and their lives and the lives of their babies.<sup>15</sup>

142. One large hospital group in Tennessee, Mountain States Health Alliance (“MSHA”), has seen a 31.3 percent increase in babies born addicted to drugs comparing a seven-month period from July 10, 2010, to Feb. 11, 2011, to the period of July 11 to Feb. 23, 2012.<sup>16</sup> The seven-month 2010-11 total was 99, versus 130 in the seven months of 2011-12.<sup>17</sup> The numbers are from Johnson City Medical Center, Indian Path Medical Center, Franklin Woods Community Hospital, the former Johnson City Specialty Hospital and Sycamore Shoals Hospital.<sup>18</sup>

143. Mountain States Health Alliance has launched an initiative targeting about 100 greater Tri-Cities physicians approved by federal authorities to dispense the drugs.<sup>19</sup>

144. In 2012, Wellmont Healthcare, a large hospital group in the Johnson City area, reported that 20 percent of the infants in Kingsport’s Holston Valley Medical Center’s Neonatal

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<sup>14</sup>Varney, D., Governor’s Safety Forum Presentation.

<sup>15</sup> *Johnson City Press*, “Women Warned Not To Use Two Drugs Around Pregnancy” March 22nd, 2012.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

Intensive Care Unit were there for neonatal abstinence syndrome (from opiate addiction or treatment), and that the longest treatment for those has been 45 days.<sup>20</sup>

145. Even in the face of this human catastrophe that has been unfolding for more than ten years, standard of care MMT exists nowhere in the Proposed Service Area.

146. For more than 40 years, MMT has been recognized as the standard of care treatment for opiate addiction by health authorities in the United States and around the world.

147. Almost all health authorities in the United States and around the world who have spoken on the issue have declared that MMT is the standard of care treatment for opiate addiction with a record of safety and effectiveness unmatched by any other treatment.

148. Doctors in the United States, and around world, prescribe MMT for more than 1,000,000 patients every day.

149. At the CON hearing, TCH presented uncontroverted evidence that MMT has been recognized as “effective” and/or the standard of care treatment for opiate addiction for 40 years or more by numerous United States and world health authorities. Accordingly, TCH presented the following slide at the CON hearing:

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<sup>20</sup> *Id.*

## **The Standard of Care for Opiate Addiction is Methadone Maintenance Treatment**

**METHADONE HAS BEEN ENDORSED AS THE "STANDARD OF CARE" FOR  
OPIATE ADDICTION – AND ESPECIALLY FOR PREGNANT WOMEN – BY:**

**NATIONAL INSTITUTE OF HEALTH (NIH)**

**NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)**

**U.S. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)**

**AMERICAN SOCIETY OF ADDICTION MEDICINE**

**CENTER FOR DISEASE CONTROL (CDC)**

**WORLD HEALTH ORGANIZATION (WHO)**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

**AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS**

**NEW ENGLAND JOURNAL OF MEDICINE**

**JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (AMA)**

Source: National Institute of Health (NIH.gov); National Institute on Drug Abuse (NIDA.gov); 2; U.S. Substance Abuse & Mental Health Services Administration (SAMHSA.gov); Center for Disease Control (www.cdc.gov); The World Health Organization (WHO.org); The New England Journal of Medicine (JAMAnetwork.org); Journal of the American Medical Association (AMA-assn.org); American College of Obstetricians and Gynecologists (acog.org); HHS.gov.

150. Specifically, the following health organizations have described MMT as either “the standard of care,” “the most effective treatment,” or “an effective treatment” for opiate addiction:<sup>21</sup>

NATIONAL INSTITUTE OF HEALTH (NIH)<sup>22</sup>

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)<sup>23</sup>

<sup>21</sup> National Institute of Health (NIH.gov); National Institute on Drug Abuse (NIDA.gov). 2; U.S. Substance Abuse & Mental Health Services Administration (SAMHSA.gov); Center for Disease Control (www.cdc.gov); The World Health Organization (WHO.org); The New England Journal of Medicine (JAMAnetwork.org); Journal of the American Medical Association (AMA-assn.org); American College of Obstetricians and Gynecologists (acog.org); HHS.gov.

<sup>22</sup> “Methadone maintenance treatment has the longest successful track record in patients addicted to opioids for more than a year and has been shown to control withdrawal symptoms, stabilize physiologic processes, and improve functionality.” Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Treatment Improvement Protocol (TIP) Series, No. 43, National Institute of Health (2013) (<http://www.ncbi.nlm.nih.gov/books/NBK64152/>).

<sup>23</sup> “An overview of 5 meta-analyses and systematic reviews, summarizing results from 52 studies and 12,075 opioid-dependent participants, found that when methadone maintenance treatment was compared with methadone detoxification treatment, no treatment, different



U.S. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMINISTRATION

(SAMHSA)<sup>24</sup>

AMERICAN SOCIETY OF ADDICTION MEDICINE<sup>25</sup>

CENTER FOR DISEASE CONTROL (CDC)<sup>26</sup>

WORLD HEALTH ORGANIZATION (WHO)<sup>27</sup>

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)<sup>28</sup>

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS<sup>29</sup>

NEW ENGLAND JOURNAL OF MEDICINE<sup>30</sup>

JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (AMA)<sup>31</sup>

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dosages of methadone, buprenorphine maintenance treatment, heroin maintenance treatment, and L-aacetylmethadol (LAAM) maintenance treatment, methadone maintenance treatment (MMT) was more effective than detoxification, no treatment, buprenorphine, LAAM, and heroin plus methadone. High doses of methadone are more effective than medium and low doses (Amato, Davoli, Perucci, et al., 2005)” National Institute on Drug Abuse, Methadone Research Web Guide, <http://international.drugabuse.gov/sites/default/files/pdf/partb.pdf>; “Methadone treatment has been used for more than 30 years to effectively and safely treat opioid addiction.” National Institute on Drug Abuse (2012), <http://www.drugabuse.gov/publications/research-reports/heroin-abuse-addiction/what-are-treatments-heroin-addiction>).

<sup>24</sup> Medication Assisted Recovery Treatment for the 21<sup>st</sup> Century: A Community Education Kit (2003).

<sup>25</sup> Public Policy Statement on Methadone Treatment of Addiction, ASAM.org, April 1, 1990; rev. October 1, 2006.

<sup>26</sup> Methadone Maintenance Treatment, Center for Disease Control (2002) (“Methadone maintenance treatment is the most effective treatment for opioid addiction.”), <http://www.cdc.gov/idu/facts/methadonefin.pdf>

<sup>27</sup> Bulletin of the World Health Organization Past issues Volume 86: 2008 Volume 86, Number 3, March 2008, 161-240 (“[M]ethadone maintenance treatment – a treatment that has been around for over 40 years – is still regarded as the most effective.”).

<sup>28</sup> Medication Assisted Recovery Treatment for the 21<sup>st</sup> Century: A Community Education Kit (2003).

<sup>29</sup> ACOG, Committee on Health Care for Underserved Women and the American Society of Addiction Medicine, Opinion Number 524, May 2012.

<sup>30</sup> N Engl J Med 2010; 363:2320-2331 (buprenorphine is an “alternative treatment” to methadone).

<sup>31</sup> JAMA, March 8, 2000, Vol 283, No. 10 (“Our results confirm the usefulness of [Methadone

151. MMT is the unquestioned standard of care for opiate-addicted pregnant women.

152. At the CON hearing, TCH presented the panel with undisputed evidence that MMT is unquestionably the standard of care for opiate addicted pregnant women.

**Methadone is the Standard of Care with Opiate-Addicted Pregnant Women**

"Opioid use is not uncommon in pregnancy. The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone."

"Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal [death]."

American College of Obstetricians and Gynecologists (2012).

"Methadone is the recommended treatment for opioid dependence during pregnancy."

Journal of the American Medical Association, April 30, 2012.

"The standard of care for opiate addiction during pregnancy is methadone maintenance and psychiatric care."

New England Journal of Medicine 363:24 (nejm.org) December 9, 2010.

"Methadone is the standard of care in pregnant women with opioid addiction."

National Institute of Health (NIH) Consensus Panel (1998)

"Methadone has been the standard of care for the past 40 years for opioid-dependent pregnant women."<sup>4</sup>

National Institute on Drug Abuse (2012).

Source: 1. American College of Obstetricians and Gynecologists (2012). 2 3. 4. National Institute of Health (NIH) Consensus Panel (1998). 5. National Institute on Drug Abuse (2012).

153. In 2012, the American College of Obstetricians and Gynecologists declared in a formal published opinion that MMT is the standard of care for opiate addicted pregnant women:

154. "Opioid use is not uncommon in pregnancy.... The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone.... Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal [death]."

155. "Opioid Abuse, Dependence, And Addiction In Pregnancy," American College of Obstetricians and Gynecologists Committee Opinion No. 524 (2012)(emphasis added).

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Maintenance Treatment] in reducing heroin use and HIV risk behaviors.").

156. On or about April 30, 2012, the Journal of the American Medical Association declared: “[M]ethadone is the recommended treatment for opioid dependence during pregnancy.”

157. On December 9, 2010, New England Journal of Medicine declared: “[T]he standard of care for opiate addiction during pregnancy is methadone maintenance and psychiatric care.”<sup>32</sup>

158. In 1998, a National Institute of Health (NIH) Consensus Panel declared: “[M]ethadone is the standard of care in pregnant women with opioid addiction.”

159. In 2012, the National Institute on Drug Abuse declared: “[M]ethadone has been the standard of care for the past 40 years for opioid dependent pregnant women.”

160. Even Johnson City’s own large hospital group, MSHA, declared in a 2012 to more than 100 doctors in the area that “Methadone is the recommended medication used for detoxification during pregnancy.”<sup>33</sup>

161. Thus, MMT is the standard of care for opiated-addicted pregnant women.

162. Furthermore, MMT is the standard of care for opiated-addicted pregnant women because, among other reasons, it offers a generally higher treatment retention rate – and a generally lower relapse rate—than other treatment methods, including buprenorphine/Suboxone/Subutex.

163. Opiate-addicted mothers treated with non-MMT treatments, such as buprenorphine (Subutex and Suboxone), generally have a lower rate of retention in treatment and a higher rate of relapse.

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<sup>32</sup> New England Journal of Medicine, Vol. 363:24 (2010)([nejm.org](http://nejm.org)).

<sup>33</sup> “Women Warned Not to Take Two Drugs Around Pregnancy,” *Johnson City Press*, March 22, 2012. (<http://www.johnsoncitypress.com/article/99175>)

164. Opiate addiction relapse is associated with increased risk of withdrawal and fetal death.

165. MMT for pregnant women, methadone is so crucial for protection of the mother and baby that the U.S. Department of Health and Human Services issued a special pamphlet alerting doctors and their pregnant patients that “Methadone Can Save Your Baby’s Life.”<sup>34</sup> This message was shown to the CON panel.

Slide 26

**United States Dept. of Health and Human Services:  
“Methadone Can Save Your Baby’s Life”**

- “Methadone Maintenance Treatment can prevent the withdrawal symptoms many drug users experience.”
- “Withdrawal for pregnant women is especially dangerous because it causes the uterus to contract and may bring on miscarriage or premature birth.”
- “By blocking withdrawal symptoms, Methadone Maintenance Treatment can save your baby’s life.”
- “Additionally, Methadone Maintenance Treatment can help you stop using needles, which is a primary route of infection for drug users.”
- “More importantly, it can allow you to regain your quality of life.”

Source: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Substance Abuse and Mental Health Services Administration  
Center for Substance Abuse Treatment  
[www.samhsa.gov](http://www.samhsa.gov)

166. Opioid withdrawal symptoms drive the addiction to opiates.<sup>35</sup>

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<sup>34</sup> U.S. Dept. of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (2013)([www.samhsa.gov](http://www.samhsa.gov)).

<sup>35</sup> The U.N. Human Rights Council has even gone so far as to describe denial of opiate replacement therapy as “possibly torture:”

“A particular form of ill-treatment and possibly torture of drug users is the denial of opiate substitution treatment, including as a way of eliciting criminal confessions through inducing painful withdrawal symptoms (A/HRC/10/44 and Corr.1, para. 57). The denial of methadone treatment

167. Relapse and withdrawal in an opiate-addicted pregnant woman can cause miscarriage and fetal death.

168. MMT provides mothers with a lower risk of fetal death due to relapse or withdrawal than alternative treatments, such as buprenorphine and its branded formulations Subutex (buprenorphine) or Suboxone (buprenorphine/naloxone).<sup>36</sup>

169. Buprenorphine and Suboxone (buprenorphine/naloxone) can precipitate the opioid withdrawal syndrome.

170. Opiate withdrawal syndrome can be precipitated in individuals maintained on buprenorphine.

171. Use of buprenorphine on persons physically dependent on full-agonist opioids, while not already in withdrawal, may trigger an extremely intense form of opioid withdrawal – called "precipitated withdrawal" or "precipitated withdrawal syndrome."

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in custodial settings has been declared to be a violation of the right to be free from torture and ill-treatment in certain circumstances (ibid., para. 71). Similar reasoning should apply to the non-custodial context, particularly in instances where Governments impose a complete ban on substitution treatment and harm reduction measures."

See HRW, Lessons Not Learned: Human Rights Abuses and HIV/AIDS in the Russian Federation (2004). United Nations Human Rights Council, Twenty-second session, Agenda item 3, "Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez," A/HRC/22/53 (2013).

<sup>36</sup> In October 2002, the Food and Drug Administration (FDA) of the United States also approved Suboxone and Subutex, buprenorphine's high-dose sublingual tablet preparations indicated for detoxification and long-term replacement therapy in opioid dependency, and the drug is now used predominantly for this purpose. Subutex contains only buprenorphine hydrochloride. Suboxone contains an additional ingredient called naloxone to guard against misuse, but this can induce potentially dangerous opioid withdrawal syndrome.

172. Precipitated withdrawal syndrome does not occur in all persons tolerant to full-agonist opioids, but rather depends on the severity of dependence and time elapsed from their last dose. For example, a hardcore heroin addict has a higher risk of precipitated withdrawal syndrome if given buprenorphine than a less severe case.

173. Precipitated withdrawal syndrome in opioid addicted pregnant women can result in premature birth or miscarriage.

174. Side effects of buprenorphine can include nausea, vomiting, and constipation.

175. Because of possible negative interaction with other medications a patient may already be taking, buprenorphine (including Subxone and Subutex) is an inappropriate treatment option for some opiate addicted patients who may be better suited for MMT.

176. Because of certain medical conditions in some patients, buprenorphine (including Subxone and Subutex) is an inappropriate treatment option for some opiate addicted patients who may be better suited for MMT.

177. Because of its generally lower retention rate than MMT, buprenorphine (including Subxone and Subutex) is an inappropriate treatment option for some opiate addicted patients who may be better suited for MMT.

178. Because of its generally higher relapse rate than MMT, buprenorphine (including Subxone and Subutex) is an inappropriate treatment option for some opiate addicted patients who may be better suited for MMT.

179. Because of a significant possibility of opioid withdrawal syndrome in some patients, buprenorphine (including Subxone and Subutex) is an inappropriate treatment option for some opiate addicted patients who may be better suited for MMT.

180. Because of its possible negative side effects in some patients, buprenorphine (including Subxone and Subutex) is an inappropriate treatment for some opiate addicted patients who may be better suited for MMT.

181. Because of the risk of opioid withdrawal syndrome, buprenorphine (including Subxone and Subutex) is an inappropriate treatment for a significant number of opiate addicted patients, particularly those patients with a more severe dependence and history of opioid use (i.e., a hardcore heroin user) who are better suited for MMT.

182. Methadone Maintenance Treatment (MMT) is a life-saving treatment that is proven to reduce deaths from drug overdoses.

183. In 2012, the World Health Organization issued a bulletin that “[MMT] dramatically reduces deaths from drug overdoses....”<sup>37</sup>

184. In 2013, the Journal of Addiction reported an apparent ten-fold decrease in chance of death for those patients in MMT treatment versus those on the waiting list for MMT treatment.<sup>38</sup>

185. In 2010, the British Medical Journal reported that MMT has been demonstrated to improve the survival chances of drug users and prevents addiction-related deaths.<sup>39</sup>

186. In 2010, the British Medical Journal reported that patients in MMT tended to use heroin less frequently, and that the treatment was associated with a 13 per cent reduced risk of death each year.<sup>40</sup>

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<sup>37</sup> World Health Organization (<http://www.who.int/bulletin/volumes/91/2/12-109132/en/index.html>), Hedrich D, Alves P, Farrell M, Stöver H, Møller L, Mayet S. The Effectiveness of Opioid Maintenance Treatment in Prison Settings: A Systematic Review. *Addiction* 2012; 107:501–17.

<sup>38</sup> *J Addict Med.* 2013 May-Jun 7(3):177-82.

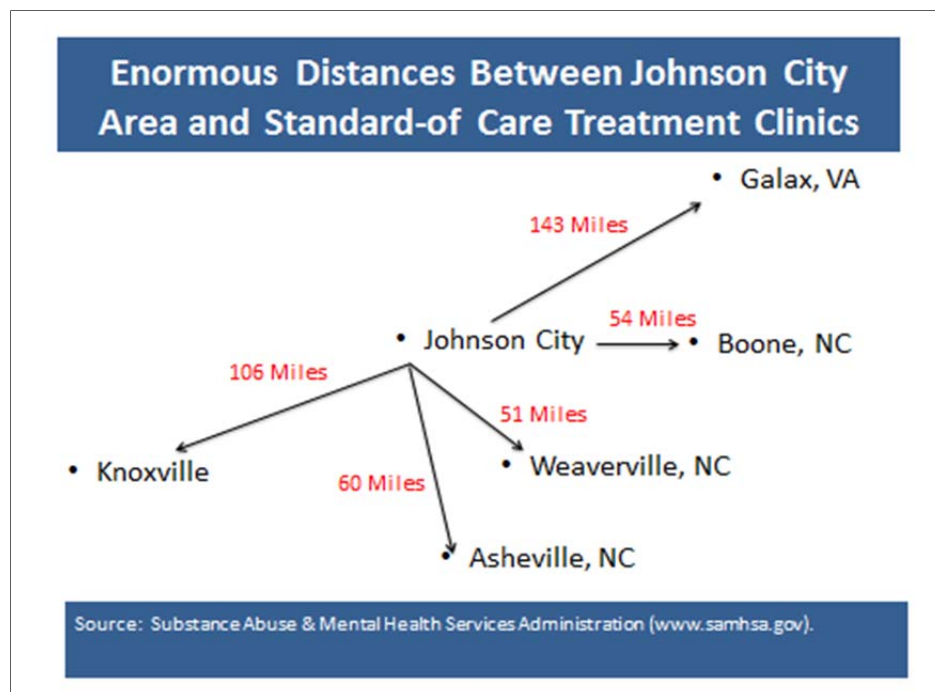
<sup>39</sup> Research: Risk Of Death During And After Opiate Substitution Treatment In Primary Care: Prospective Observational Study In UK General Practice Research Database, *BMJ* 341: c5475 (2010).

187. In 2004, a U.S. Health and Human Services Department study found that OTPs were not a significant factor in increases in methadone-related deaths, those deaths being caused by increased use of a methadone as an analgesic (i.e., pain management) and not in MMT.<sup>41</sup>

188. A recovering opiate addict, stabilized in MMT treatment, faces a substantially lower chance of death, compared to an opiate addict continuing to use illegal sources of opiates-- such as heroin.

**189. Standard of Care MMT Clinics are nowhere in the Proposed Service Area.**

190. Undisputed evidence at the CON hearing showed that all MMT clinics are more than 100 miles away roundtrip from large parts of the Proposed Service Area as shown by the slide below.



191. Distance is a barrier to opiate addiction treatment.

<sup>40</sup> 4. Survival and Cessation In Injecting Drug Users: Prospective Observational Study of Outcomes and Effect of Opiate Substitution Treatment, BMJ 341 (2010).

<sup>41</sup> Methadone-Associated Mortality: Report of a National Assessment, U.S. Dept. Health Humans Services (2004)(Part 4)



192. Forcing someone to drive more than 100 miles a day for more than a few days, much less 90 straight days or more, is a denial of reasonable access to medical treatment.

193. Due to the overwhelming costs and time of driving over 100 miles per day for treatment, recovering addicts in East Tennessee are largely unable to remain in MMT programs. Distance is a barrier to opiate addiction treatment.

194. The 2001 Tennessee Methadone Task Force confirmed this common sense notion of “distance is a barrier to treatment” with hard data in that “[g]enerally, the closer one lives to a treatment program, the greater likelihood of participation....The rate of participation is nearly twice as high for persons living in or close to one of the five counties that house programs, 59.0/100,000, than the rate for those that live 60 miles or more from a program, 32.2/100,000.”.

195. Medical experts presented by TCH and Johnson City on May 24, 2013 both testified that making an opiate-addicted person drive 100 miles round trip to receive doctor prescribed, lifesaving MMT treatment is equivalent to a denial of medical treatment.<sup>42</sup>

196. The Individual Plaintiffs’ drive to out-of-state OTP clinics must be made as often as daily to avoid serious withdrawal symptoms common to opiate-addicted persons.<sup>43</sup>

197. The Individual Plaintiffs—and hundreds like them—are expending enormous amounts time and expense in gasoline, wear on their automobiles, exhaustion from having to wake up as early as 1-4AM to get up, dress themselves and their children, place their children into car seats, and drive these enormous distances as often daily.

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<sup>42</sup> *Tri-Cities Holdings et al. v. Johnson City et al.*, Case No. 13-cv-108 (E.D. Tenn. 2013)(case dismissed without prejudice on ripeness grounds), Testimony of Dr. Robert Newman, May 24, 2013, at p. 32; Testimony of Dr. Stephen Loyd, May 24, 2013, p. 30, l. 9-13.

<sup>43</sup> National Institute of Drug Abuse at the National Institute of Health (<http://www.drugabuse.gov/drugs-abuse>).

198. All this driving consumes time and money that clearly could be devoted to family and work—all for treatment of a disability unquestionably recognized under the ADA and the RA.

199. At least 400-500 ADA-disabled persons are being denied reasonable access to standard of care MMT treatment in the Proposed Service Area.

200. At least 400-500 East Tennessee residents in the Proposed Service Area are having to wake up between 1AM-4AM, as often as daily, and then drive to distant OTP clinics in North Carolina, then drive home and prepare for work.

201. These persons, disabled under federal law, presently endure a driving marathon of 100 miles or more roundtrip to out-of-state OTP clinics offering the closest standard of care MMT as often as every day.

202. In an email, HSDA staff dubbed this daily mass movement of humans as a “migration.”

203. In a June 24, 2013, Spencer Clark, Director of the North Carolina Opioid Treatment Authority, confirmed in writing of the existence of the 400-500 person “migration” and that the number “may be higher.” This so-called “migration” occurs every day, in the wee hours of the morning, on mountain roads, in all weather conditions, and certainly including instances of dangerous driving conditions during rain, sleet or snow.

204. TCH presented testimony at the CON hearing that this number is likely underreported and probably closer between 1,000 and 1,500.

205. Therefore, at least 400-500 ADA-disabled persons--and possibly 1,000 to 1,500--are being forced, often as daily, as to drive more than 100 miles roundtrip for doctor-prescribed, life-saving, standard of care treatment that is available nowhere in the Proposed Service Area.

206. State and federal regulations require that new MMT patients, including pregnant women, are required to obtain medication in person at an MMT clinic for at least the first 90 days straight with no ability to take home any medication—even one day's worth.

207. Therefore, new MMT patients in the Proposed Service Area, including pregnant women, who are seeking treatment for first time to break their potentially deadly opiate addiction, are required to drive up to 9,000 miles, or more, in the first 90 days of treatment to obtain doctor-prescribed MMT treatment.

208. The Individual Plaintiffs, and certainly 400-500 disabled persons--and possibly over 1,000--people like them—are effectively being denied access by HSDA and Johnson City to doctor-prescribed, life-saving standard of care MMT medication for their disability.

209. There exist significant risks when driving on East Tennessee mountain roads during inclement weather such as rain, sleet or snow.

210. The lack of reasonable access to MMT treatment risks of severe physical injury or death including the risk of withdrawal, relapse, and the risks of traveling on potentially dangerous mountain roads to distant MMT clinics in North Carolina in all weather conditions including rain and snow.

211. The lack of reasonable access to MMT treatment presents a clear and present danger to the Individual Plaintiffs and others, including pregnant women and their unborn babies.

212. Highway deaths are occurring on East Tennessee roads because disabled people are being forced to make grueling 100-plus roundtrip journeys, as often as daily, to OTP clinics in North Carolina for the closest standard of care MMT.

213. Drives face significant increased risks of an accident when they are significantly deprived of sleep, such as having to wake up at between 1AM and 4AM and drive 50+ miles from Johnson City to a distant OTP clinic in North Carolina to enable them to obtain their MMT medication, then drive 50+ miles back to Johnson City, and then go to work.

214. It is undisputed that 400-500 disabled people in East Tennessee (and probably over 1,000) being forced to seek doctor-prescribed, standard of care MMT treatment in distant out-of-state OTPs are causing traffic deaths.

215. Therefore, it is undisputed that people are dying because 400-500 recovering opioid addicts are being forced to exhaust themselves driving hundreds of miles, sometimes at all hours of the morning, as often as every day, to reach distant out-of-state OTP clinics.

216. Tragically, some people just give up trying to get better in the face of this astronomical driving burden required of disabled persons in Johnson City to stay in standard of care MMT treatment.

217. Instead, these recovering addicts may simply go back to what is certainly much more convenient legal supplies of opiates from pain clinics (so-called "pill mills")--that permeate the Johnson City area, or the increasing supplies of illegal opiates such as heroin.

218. Dropping out of MMT and returning to pain pills or heroin can lead to horrible results and huge costs for people individually and for society as a whole.

219. TCH's proposed clinic in this area will be a life-saver to the Individual Plaintiffs - --and hundreds like them-- in that it will reduce the astronomical distances they must drive as often as daily for doctor-prescribed MMT and the enormous toll such driving takes.

220. The HSDA panel was clearly made aware of the fact that a recovering opiate-addicted persons, including pregnant women, must drive 100 miles per day for doctor-

prescribed, standard-of-care, life-saving treatment during up to the first three months (90 days) of MMT treatment because it is nowhere available in the Proposed Service Area.

221. Requiring any person, without reason, to drive more than 100 miles roundtrip daily for medication that best offers to save their life imposes a sadistic, unnecessary burden on that person. Imposing this unnecessary burden on a disabled opiate addicted person, and on disabled pregnant woman at that, is outrageous.

222. As such, HSDA and Johnson City's refusal to allow life-saving, doctor-prescribed, standard of care MMT medication to be available in the Proposed Service Area to the Individual Plaintiffs and hundreds like them, is a clear violation of the ADA and RA.

223. On June 26, 2013, HSDA's board considered TCH's CON application at a more than four-hour-long hearing held in Nashville, Tennessee ("CON hearing") in which large numbers of Johnson City residents appeared (approx. 25) and spoke (approx. 10) in an attempt to block TCH's CON application.

224. During the CON hearing, the opponents of TCH's CON application--led by officials of the Johnson City government, including Mayor Van Brocklin, introduced evidence that the relatively new and untested methadone substitute -- buprenorphine -- and its branded formulations Subutex and Suboxone, were somehow equivalent in every way to MMT in safety and effectiveness. This is unquestionably false as these relatively risky, untested, and non-standard of care drugs are shown, at the very minimum, to be inferior to MMT for retaining patients in treatment which reduces the risk of potentially deadly relapses.

225. On average, more than 80% of OTP patients are prescribed methadone rather than less effective, and more costly, non-standard of care medications such as buprenorphine/Subutex/Suboxone.

226. Studies have shown that another MMT alternative, so-called “abstinence-based therapy” incurs potentially deadly relapse rates running up to 75-90% or more.

227. Abstinence-based therapy is definitely not the standard of care for pregnant women because it carries an extremely high chance of relapse and withdrawal (opioid withdrawal syndrome) which is associated with fetal death.

228. In fact, in 2012, Mountain States Health Alliance, a large multi-hospital health provider in the Johnson City area, specifically warned doctors not to employ buprenorphine/Subutex/Suboxone with opiate-addicted pregnant women.

229. Details of the Mountain States Health Alliance warning was presented to the panel at the CON hearing.

230. The Mountain States Health Alliance warning to area doctors not to employ buprenorphine (Suboxone or Subutex) was covered in the Johnson City Press newspaper on March 22, 2012 and read in part as follows:

“If you are pregnant, trying to get pregnant or not using birth control, don’t take Subutex or Suboxone, for the sake of your unborn child.”

\* \* \*

“And if you are a physician, don’t continue to prescribe those drugs containing buprenorphine to anyone who is pregnant.

\* \* \*

“Dr. Joy Anderson, a Mountain States Medical Group obstetrician and gynecologist practicing in Kingsport, said pregnant women are being told by physicians prescribing the two drugs ‘it’s a safe drug in pregnancy’ when it is not.

\* \* \*

“Methadone is the recommended medication used for detoxification during pregnancy, the MSHA literature says.”

“Women Warned Not to Take Two Drugs Around Pregnancy,” Johnson City Press, March 22, 2012. (<http://www.johnsoncitypress.com/article/99175>)(emphasis added).

231. HSDA should have approved TCH’s CON application because it satisfied all criteria required by Tennessee law to empower HSDA to grant the CON, including satisfying the criteria of need, economic feasibility, and orderly development.

232. However, on June 26, 2013, HSDA denied TCH’s CON application.

233. In doing so, the HSDA panel did not comply with Plaintiffs’ request for a reasonable accommodation to grant the Certificate of Need (“CON”) under the ADA and the RA.

234. The following facts were undisputed at the CON hearing:

235. MMT is the standard of care for treatment of opiate addiction.

236. MMT is the standard of care for opiate addicted pregnant women by offering the lowest risk of relapse, withdrawal, and fetal death, among other reasons.

237. MMT is not available anywhere in the Proposed Service Area.

238. HSDA failed to make a reasonable accommodation to allow TCH to obtain a CON and establish in OTP in Johnson City.

239. On June 26, 2013, HSDA’s board considered TCH’s CON application at a public hearing held in Nashville, Tennessee (“CON hearing”).

240. On or about June 18, 2013, TCH and the Individual Plaintiffs specifically requested by letter that HSDA provide TCH with a reasonable modification of HSDA rules under the ADA and RA to allow the granting of TCH’s CON application.

241. At the CON hearing, TCH and the Individual Plaintiffs specifically requested that HSDA provided TCH with a reasonable modification of HSDA rules under the ADA and RA to allow the granting of TCH’s CON application.

242. On or about June 28, 2013, TCH and the Individual Plaintiffs specifically requested by letter that HSDA provided TCH with a reasonable modification of HSDA rules under the ADA and RA to allow the granting of TCH's CON application.

243. The HSDA panel voted 6-2 against TCH's CON application with six members voting against, two members voting in favor, and one panel member abstaining.

244. At the conclusion of the CON hearing, the panel Chairman directed TCH and the Individual Plaintiffs' attorney to contact HSDA staff to pursue a request for a reasonable modification or accommodation under the ADA and the RA.

245. TCH's proposed clinic will allow the Individual Plaintiffs--along with hundreds of other similarly disabled area residents which include pregnant women – to finally have access to doctor-prescribed, life-saving, standard of care MMT for in the Proposed Service Area.

246. HSDA could easily, and without undue burden, modify one or all of the criteria related to need, economic feasibility, and orderly development (and for that matter, any and all other rules, if any, presently stopping the CON from being issued) and allow the CON application to be approved.

247. HSDA has failed to offer TCH a modification of its rules if necessary to allow TCH to provide disabled persons reasonable access to standard of care MMT treatment in the Proposed Service Area.

248. There is widespread community animus in Johnson City against TCH's proposed clinic, including thinly veiled threats of violence against me in commentary on the Johnson City Press web site.

249. In its determined and highly-organized attempt to keep recovering opiate-addicted persons from convenient access to standard of care



treatment, a large contingency of some twenty-five Johnson City residents or more accompanied Mayor Ralph Van Brocklin and City Attorney Erick Herrin to Nashville to put pressure on the CON panel to deny TCH's CON application. Many Johnson City citizens traveled to Nashville to speak out against TCH's CON application. Mayor Ralph Van Brocklin spoke out and declared to the effect that it was "not fair for Johnson City to carry all the weight of treating opiate addicted people in the whole region." (paraphrase). Thus, Johnson City seeks to build a region-serving medical industry—just not one for opiate-addicted people.

250. At the Nashville CON hearing, many, many Johnson City residents, including the HSDA panel Chairman D. Lyn Johnson, who on Plaintiffs' information and belief is from the Tri Cities area, declared that "if these people want methadone treatment, they can drive [the 100+ miles roundtrip journey] to get it, so there is patient choice." (paraphrase).

251. At the Nashville CON hearing, Johnson City went so far as to hire an attorney specializing in CON law, Mr. Jerry Taylor, of the Nashville law firm Stites & Harbinson, to combat TCH's application. At the beginning of the CON hearing, Mr. Taylor made the somewhat outlandish claim that Johnson City and the twenty-some citizens that packed the CON hearing room were *merely opposing TCH's particular CON application* and that they and Johnson City had "no problem" with methadone clinics in Johnson City in general. This contention

seems--to be charitable--“highly suspect” in the face of Johnson City’s decades-long battle against all OTP clinics and current evidence of widespread community aversion of opiate-addicted people seeking reasonable access to MMT treatment in Johnson City.

252. Attached are true and correct copies of the following exhibits.

Exhibit A-1	Johnson City Attorney James Epps Letter to Tennessee Health Services and Development Agency dated March 12, 2013.
Exhibit A	Tri-Cities Holdings LLC’s Notice of Intent to File for a Certificate of Need for Methadone Clinic in Johnson City dated March 4, 2013
Exhibit B	Johnson City Zoning Ordinance Definition of Methadone Treatment Clinic
Exhibit C	Johnson City Zoning Ordinance Related to Methadone Treatment Clinics
Exhibit D	Johnson City Zoning Map Showing the Subject Property, 4 Wesley Court
Exhibit E	Johnson City Zoning Ordinance Definition of Arterial Street
Exhibit F	Satellite Image of Subject Property, 4 Wesley Court
Exhibit G	Johnson City Zoning Ordinance Related to Special Exception Permits
Exhibit H	Johnson City Zoning Ordinance Definitions
Exhibit I	Tri-Cities Letter to Johnson City Attorney James Epps dated March 15, 2013.
Exhibit J	Tri-Cities Holdings LLC’s Request for Zoning Variance and Accommodation under ADA
Exhibit K	Johnson City Zoning Map

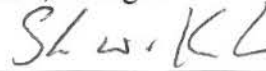
And Johnson City Zoning Ordinance (Complete)

Exhibit L	April 9, 2013 Johnson City Board of Zoning Appeals Hearing on TCH Application of Zoning Variances
Exhibit M	Newspaper Articles and University of Tennessee Municipal Technical Advisory Service Memo
Exhibit N	Tennessee Health Services and Development Agency Criteria for Certificate of Need
Exhibit O	Tennessee Health's Guidelines for Growth
Exhibit P	Washington County, Tennessee, No. 13-03-20, Resolution Opposing Methadone Clinic
Exhibit Q	Articles on Public Opposition to Methadone Clinics
Exhibit R	Prescription Drugs: Abuse and Addiction—National Institute on Drug Abuse (2011)
Exhibit S	20 Questions and Answers Regarding Methadone Maintenance Treatment Research--National Institute on Drug Abuse (2013)
Exhibit T	Influence of Distance on Mental Health Aftercare—Addictive Behaviors (2003)
Exhibit U	Study of Crime Near Methadone Clinics—University of Maryland Medical School (2011)
Exhibit V	Suboxone Label Information from U.S. Food and Drug Administration
Exhibit W	Methadone Maintenance Treatment – Center for Disease Control (2012).
Exhibit X	Methadone Treatment For Opiate Addiction Lowers Health Care Costs And Reduces Arrests And Convictions – Washington State Department of Social and Health Services (2004).
Exhibit Y	Populations at Risk for Opioid Overdose—National Center for Injury Prevention and Control (2012)

Exhibit Z	Prescription Drug Abuse and the Pill Pipeline in Appalachia—Assoc. Professor Robert Pack, East Tennessee State University (2005).
Exhibit BB	Epidemic of Prescription Opiate Abuse and Neonatal Abstinence—Journal of the American Medical Association (2012).
Exhibit CC	Tennessee Governor’s Safety Subcabinet Working Group Presentation Prescription Drug Abuse in Tennessee (2012)
Exhibit DD	Plaintiffs’ Letter to HSDA Requesting Reasonable Modification dated June 18, 2013
Exhibit EE	Plaintiffs’ Letter to HSDA Requesting Reasonable Modification dated June 28, 2013
Exhibit FF	Testimony of Testimony of Dr. Robert G. Newman, M.D., M.P.H., May 24, 2013
Exhibit GG	Testimony of Testimony of Steven Neilson, May 24, 2013
Exhibit HH	Testimony of Testimony of Steve Kester, May 24, 2013
Exhibit JJ	Testimony of Testimony of Dr. Stephen Loyd, May 24, 2013
Exhibit KK	Resume of Dr. Robert G. Newman, M.D., M.P.H.
Exhibit LL	Ordinance No. 3899—Amendment to Johnson City Methadone Clinic Zoning Requirements, passed October 17, 2002.
Exhibit MM	Johnson City Zoning Map
Exhibit NN	Tri-Cities Holdings LLC Application for a Certificate Need
Exhibit OO	U.S. Department of Health and Human Services “Methadone Can Save Your Baby’s Life”
Exhibit PP	Threat of Violence Against Steve Kester in Commentary Section <i>Johnson City Press</i> , May 31, 2013
Exhibit QQ	Medical Groups Oppose Proposed Johnson City Methadone, <i>Kingsport Times-News</i> , April 15, 2002.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 31th day of July, 2013 in Atlanta, Georgia.



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Steven W. Kester

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